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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,848	01/14/1999	TERUAKI SEKINE	1208/P502PCT	8123

7590 03/21/2003

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/214,848

Applicant(s)

SEKINE, TERUAKI

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The request filed on 1/13/2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/213,848 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating viral infections, does not reasonably provide enablement for preventing viral infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is directed to compositions and methods of treating or preventing viral infections with activated autologous lymphocytes from a virally infected patient or an immunodeficient or immunosuppressed patient. The prior art of record indicates that activated lymphocytes work by recognition and lysis of virally infected cells and provides evidence of treatment of viral diseases. Applicant's reference to the use of activated lymphocytes against CMV and the working examples in the specification appear to be limited to treatment of specific viral infections and not prevention of viral infections. Further, it does not appear based on the prior art of record and guidance provided by Applicant, that one of ordinary skill in the art could predict from treatment of a viral infection that the claimed invention would be effective in preventing viral infections as the mechanism of action of the activated lymphocytes appears to be

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recognition and lysis of infected cells. As such, one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-29,33 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Koenig et al.

Koenig et al. expressly discloses compositions comprising autologous lymphocytes from an AIDS patient activated with IL-2 and OKT3 which activated autologous lymphocytes were resuspended in normal saline and human serum albumin and reinfused into the patient in doses of 28×10^9 , 12×10^9 and 13×10^9 for treatment of the patient's HIV infection falling within the scope of applicant's claims (Pg. 334-335).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67,

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205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978) and *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 12-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Ochoa et al.* (U.S. Pat. 5,443,983) in view of *Rosenberg* for the reasons of record set forth in the prior Office Actions in further view of *Melder et al.* and the further reasons below.

Ochoa et al. (U.S. Pat. 5,443,983) and *Rosenberg* were discussed in the prior Office Action and the same are incorporated herein.

Melder et al. teaches that natural killer (NK) cells have been shown to aid in the control of viral infections by killing virus-infected cells, including cells infected with HIV (pg. 1011). It is further taught that the lymphokine activated killer (LAK) cells, activated with IL-2, were effective against HIV-infected cells and that the LAK cells which killed HIV-infected target cells were the same as those that kill tumor target cells (pg. 1014). It is taught that a generalized cytotoxic action of NK cells occurs (pg. 1014). It is further taught that cytotoxic lymphocytes are able to recognize cells infected by cytomegalovirus (pg. 1014).

Applicant's arguments have been duly considered but they are deemed unpersuasive.

Applicant argues that one of ordinary skill in the art would not expect that autologous lymphocytes would be effective against viral infections based on the *Nature Medicine* article. However, the *Nature Medicine* article is only a single article, is limited to HIV and a single patient, and did appear to conclude that treatment of with autologous lymphocytes would not be effective in treating viral infections but only that there were a number of factors which could have contributed to the adverse result in the patient tested (Pg. 332). Further, the *Nature Medicine* article specifically indicated that adoptive transfer of human cytomegalovirus specific CTL clones has yielded encouraging results and that the HIV infected patient's clinical

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deterioration might have been more accelerated without the treatment (pgs. 332, 334).

Applicant argues that Rosenberg only mentions viral infections in passing and does not contain any data or teaching which prove and enable one skilled in the art to make and/or use the invention. However, this is not the test for enablement. See MPEP Sections 2164.01 and 2121.01. In any case, the prior art does enable one skilled in the art to make and/or use the invention in that the use of autologous lymphocytes are suggested in viral, autoimmune diseases and correction of immune-deficiency diseases and methods of activation of lymphocytes and administration of the same are taught (See Rosenberg, Column 4, lines 17-55). Further, the prior art teaches that IL-2 stimulated lymphocytes are effective against HIV infected cells (See Melder et al., entire reference). In any case, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that Examiner has not specifically pointed out in the present and past Official Actions wherein each of the cited references, the limitations of the dependent claims are present. It is uncertain what Applicant means. If Applicant means the dependent claims present in the present Amendment, Examiner notes that the limitations of the present dependent claims were not claimed in the prior Amendments or the original claims. In any case, the prior art

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teaches or suggests the addition of protein, including human albumin, to the cell-suspended solution, addition of cytokines and suspension of lymphocytes in a buffer solution of physiological saline or phosphate buffer and administration of the same to the patient, and cell concentrations to be administered to the patient. See Ochoa et al. (US Pat. 5,443,983), Column 4, lines 27-34, Column 11, lines 49-68, Column 12, lines 1-50; Rosenberg, Column 4, lines 29-48)

Applicant argues that the prior art fails to suggest autologous lymphocytes, however, Rosenberg (US Pat. 4,690,915) clearly suggests the use of autologous lymphocytes (Column 4, lines 17-18). Further, one of ordinary skill in the art would expect from the teachings of Melder et al. that the activated lymphocytes, since they are effective against cancer cells, would also be effective against viruses, including herpes group viruses.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

March 12, 2003


JOHN PAK
PRIMARY EXAMINER
GROUP 1000

